

Appl. No. : **09/823,394**
Filed : **March 30, 2001**

REMARKS

Applicants wish to thank the Examiner for the courteous telephonic interview conducted on October 16, 2003 to discuss the scope of the pending claims. Claim 1 has been amended and Claims 23-30 have been added. Support for these amendments can be found on page 7, lines 18-30, page 17, lines 5-14, and page 37, lines 3-12 of the specification, for example. Claims 5 and 13-22 have been cancelled. However, Applicants expressly reserve the right to pursue these claims in a related divisional application. Accordingly, Claims 1-4, 6-12, and 23-30 are presented for examination.

Summary of Interview

During the telephonic interview conducted on October 16, 2003, Applicants representative clarified the specific variants that were disclosed in the application. Applicants representative also explained that the specification fully enabled the scope of the pending claims. The Examiner indicated that claims directed to “conservative variants” and “single amino acid variants” of SEQ ID NO: 2 may be allowable.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1-3 and 6-10 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement. The Examiner has alleged that the specification, while being enabling for substantially purified BIN1 polypeptides comprising a fragment of SEQ ID NO: 2, wherein the fragment binds brassinosteroids, does not reasonably provide enablement for other BIN1 variants. Applicants respectfully disagree.

In *Regents of University of California v. Eli Lilly & Co.*, the Federal Circuit held that enablement of a genus under § 112, ¶ 1 may be accomplished by showing the enablement of a representative number of species within that genus. 119 F.3d 1559 (Fed. Cir. 1997). Enablement “is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive.” *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). “To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without ‘undue experimentation’...Nothing more than objective enablement is required, and

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therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.” *See In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

The Examiner requested clarification regarding the locations of the variants described in the specification. As indicated above, the location of the BIN1-102 variant described on page 4, line 3 of the specification has been amended to clarify that the substitution of threonine to isoleucine actually occurs at position 750, and not position 740. As discussed below, this amendment to the specification does not add any new matter. The originally filed sequence listing indicates that position 750 of SEQ ID NO: 2 is a threonine. In addition, Applicants note that page 17, line 9 of the specification correctly indicates that the BIN1-102 variant contains a threonine to isoleucine substitution at position 750. This contrasts with the amino acid glycine that is found at position 740 of SEQ ID NO: 2. For these reasons, one of ordinary skill in the art would recognize that the position 740 on page 4, line 3, was a typographical error, and should have been 750. As page 4, line 3 of the specification has been amended to indicate the correct location of the variant, Applicants submit that any confusion as to this variant should be obviated.

The Examiner also requested clarification of the variant at position 611 described on page 7, lines 13-17 of the specification. Applicants note that this variant is different from the BIN1-6 variant at position 644, and described on page 17, line 10. Specifically, the variant at position 611 is characterized by an amino acid substitution from glycine to glutamic acid, while the BIN1-6 variant provides substitution of glycine to aspartic acid at position 644. A person with ordinary skill in the art would recognize that these are two different variants of the BIN1 polypeptide.

For the reasons provided above, Applicants respectfully submit that the BIN1 variants described in the specification are sufficiently clear to enable one of ordinary skill in the art to make and use the claimed invention. As Applicants have described multiple BIN1 variants, and an assay (Example 3, pages 49-50) for assessing their binding characteristics, a skilled artisan would be able to make and use the claimed BIN1 variants without undue experimentation.

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However, solely to advance prosecution of the present case, Applicants have amended Claim 1 to recite a substantially purified BIN1 polypeptide having the amino acid sequence of SEQ ID NO: 2, or conservative variants thereof. The Examiner indicated during the interview on October 16, 2003 that this claim language may be allowable. Support for this amendment can be found on page 37, lines 3-12 of the specification, for example. For the above stated reasons, Applicants respectfully request the withdrawal of this rejection and allowance of the pending claims.

New Claims

New Claims 23-30 have been added which recite BIN1 polypeptide having the amino acid sequence of SEQ ID NO: 2, or variants thereof, wherein a single amino acid is replaced by another amino acid. During the Interview, the Examiner indicated that this language may be allowable. Support for these claims can be found throughout the specification which lists several variants with a single amino acid replacement. For example, variant BIN1-104 is a result of replacement of the single amino acid alanine by the single amino acid threonine (page 4, lines 1-4; page 17, lines 9-12); variant BIN1-6 is a result of replacement of the single amino acid glycine by the single amino acid aspartic acid (page 4, lines 1-4; page 17, lines 12-14); variant BIN1-102 is a result of replacement of the single amino acid threonine by the single amino acid isoleucine (page 4, lines 1-4; page 17, lines 9-12) and yet another variant is the result of the replacement of the single amino acid glycine by the single amino acid glutamic acid (page 7, lines 14-15). Accordingly, new Claims 23-30 directed to variants wherein a single amino acid is replaced by another amino acid are fully supported by the specification.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention

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to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Respectfully submitted,

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Dated: November 7, 2003

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